

## **REMARKS**

Claims 1-8 are pending.

Claims 1-5 are objected to because of various informalities. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter. Claims 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter. Claims 6-8 are rejected under 35 U.S.C. 101 because of recitation of a use without setting forth any steps involved. Lastly, claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Bailey et al. (U.S. Patent No: 2002/0150653; hereinafter *Bailey*).

By way of this paper, claims 1-4, and 6-8 have been amended. Claim 11 is added new. Support for the amendment is found, among other places, in the abstract, in paragraphs [0002], [0018], [0020], [0041], and [0046], and in the claims originally filed. No new matter is introduced by this amendment.

### **Remarks Directed to Objections to Claims 1-5**

Various informalities are deemed to be found in claims 1-5 as stated on pages 2-3 of the Office action.

In response, claim 1 has been amended to correct the word "lest" with "least." Claim 2 has been amended to correct the range as "0.5-30mg, 0.1-10mg." Claim 4 has been amended to now recite "vitamin E as an antioxidant." (Emphasis Added)

Reconsideration and withdrawal of the objections to claims 1-5 is requested.

**Remarks Directed to Rejections to claims 1-5  
under 35 U.S.C. 112, first and second paragraphs**

The term "C<sub>1-8</sub> carboxylic acid" of claims 1-5 is deemed not "adequately described to convey what comprises the term" and more particularly, it is deemed unclear whether "the structure is straight .. branched . . . a single ring . . . more than one ring..." (Office action, pages 2-4). The term "dry" or "dry weight of the supplement" is deemed unclear because "the specification does not provide a standard for ascertaining the requisite degree" (Office action, page 5). The term "weight %" is deemed indefinite because it is unclear as to "what the basis of the weight percentage is" (Office action, page 6). Lastly, claims 6-8 are indefinite for reciting a use without setting forth any steps.

By convention, C<sub>1-8</sub> carboxylic acid refers to carboxylic acid having 1-8 carbon atoms. As such, the C<sub>1-8</sub> carboxylic acid structurally may not contain more than one ring, regardless if it is a 5-carbon ring or a 6-carbon ring. One example of a ring-containing C<sub>1-8</sub> carboxylic acid is a benzoic acid as indicated in paragraph [0046]. Likewise, C<sub>1-8</sub> carboxylic acid is reasonably ascertained to have a straight chain structure as indicated in the specification in view of the list including the formic acid, the citric acid, the lactic acid, the propionic acid, the ascorbic acid, the furmaric acid. *Id.* As defined in the specification originally filed and particularly in paragraph [0046], the term C<sub>1-8</sub> carboxylic acid of claim 1 may be reasonably ascertained as either straight-chained or of a ring structure. As such, requisite clarity is believed to have been provided to the term C<sub>1-8</sub> carboxylic acid as recited in claim 1.

Contrary to the contention of the Examiner, the term "dry" or "dry weight" as recited in the claims 1-5 is commonly known and widely used to mean "the mass of a material or an object when dried and without fluids." For example, the term "dry weight" is employed in the statutory language of California Code of Regulations Section 1408.3, a copy of which is submitted herewith as Exhibit A. Moreover, Applicants have conducted a search, in the United States Patent and Trademark Office patent database, using the search formula of "ACLM/"dry weight" AND ACLM/"vitamin" AND ISD/20000101->20050101. The search resulted in 17 issued patents. All the 17 patents issued by the Office recite "dry weight" as a stand-alone term

in the claims section without further elaborating "what is dry weight" or "how dry is dry" in respective specification of each of the issued patents. A copy of the search result is submitted herewith as Exhibit B. As such, Applicants submit that one skilled in the art would readily be able to ascertain that "dry weight" means the weight of a mass or an object when dried or without fluids and therefore, claims 1-5 submitted to be definite for their mere recitation of the term "dry weight."

As to the term "weight %" recited in claim 1 and claim 3 that is deemed indefinite, claims 1 and 3 have been amended accordingly, to now read "the supplement . . . contains 0.5-3.5 mg of iron fumarate per 100 mg of the supplement" for claim 1 and "0-1 mg of an antioxidant per 100 mg dry weight of the supplement" for claim 3. Support for this amendment is found, among other places, in paragraph [0020] of the specification.

As to claims 6-8 deemed indefinite for having recited the use of a supplement without setting forth any steps, claims 6-8 are now amended to be directed to a method with step(s) identified.

With the above identified claim amendments and remarks directed thereto, Applicants respectfully submit that the subject matter of claim 1-8 is entitled to patentable weight. Reconsideration and withdrawal of rejections to claims 1-5 under 35 U.S.C. 112, first and second paragraphs, and to claims 6-8 under 35 U.S.C. 112, second paragraph and under 35 U.S.C. 101 is solicited.

**Remarks Directed to Rejections to Claims 1-5 under 35 U.S.C. 102(b) over Bailey**

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by *Bailey* because *Bailey* teaches "the concept of a food, feed, and vitamin preparations comprising folates and multivitamins" (Office action, page 7).

Claim 1 in current form recites a food and feed supplement comprising "at least one C<sub>1-8</sub> carboxylic acid . . . vitamins B<sub>6</sub>, B<sub>9</sub>, and B<sub>12</sub> each in an amount of 10-50 mg/gram dry

weight of the supplement . . . 5-25 mg Fe/gram dry weight of the supplement . . . and 0-10 mg of an antioxidant per gram dry weight of the supplement."

In contrast, the feed supplement of *Bailey* is drastically different. *Bailey* fails to teach or suggest a supplement comprising a carboxylic acid, let alone specifically the C<sub>1-8</sub> carboxylic acid. *Bailey* fails to teach or suggest a supplement comprising all three B vitamins including the B<sub>6</sub>, B<sub>9</sub>, and B<sub>12</sub>, let alone the B vitamins with specified amounts as recited in claim 1. Moreover, *Bailey* fails to teach or suggest a supplement comprising an iron and an antioxidant with specified amount as indicated in claim 1. To say that *Bailey* fails to be a 102(b) prior art against the instant claims 1-5 is an understatement since *Bailey* is not even remotely related to the present invention.

*Bailey* fails to teach or suggest at least one element of the independent claim 1 and all the claims dependent therefrom are submitted to be patentable under 35 U.S.C. 102(b) over *Bailey*.

Reconsideration and withdrawal of rejections to claims 1-5 under 35 U.S.C. 102(b) over *Bailey* is solicited.

**Remarks Directed to Claim 11 Added New**

Claim 11 is added new to depend from claim 1 with particular recitation as to the C1-8 carboxylic acid. Support for the newly added claim 11 is found, among other places, in paragraph [0046] of the specification.

Allowability of claim 11 is solicited.

## CONCLUSION

Applicants have made a genuine effort to respond to each of the Examiner's rejections in advancing the prosecution of this case. Applicants believe that all formal and substantive requirements for patentability have been met and that this case is in condition for allowance, which action is respectfully requested. If a telephone or video conference would help expedite allowance or resolve any additional questions, such a conference is invited at the Examiner's convenience.

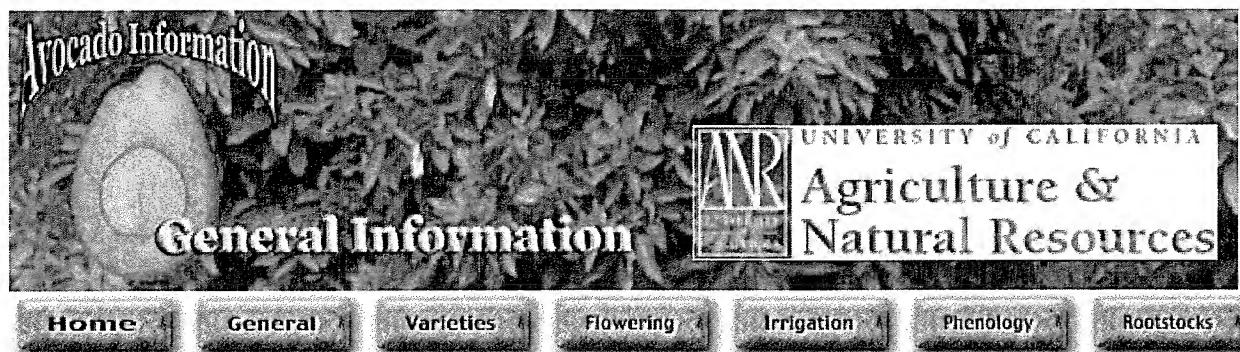
The Petition fee of \$230.00 is being charged to Deposit Account No. 02-3978 via electronic authorization submitted concurrently herewith. The Commissioner is hereby authorized to charge any additional fees or credit any overpayments as a result of the filing of this paper to Deposit Account No. 02-3978.

Respectfully submitted,  
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**DEPARTMENT OF FOOD AND AGRICULTURE  
PROPOSED CHANGES IN THE REGULATIONS**

**Title 3. California Code of Regulations  
Article 11. Avocados**

Amend Section 1408.3 to read:

**Section 1408.3. Avocados, Determination of Dry Matter.**

Dry matter of avocados shall be determined by weighing the fresh weight and dry weight of a sample of avocados. The testing procedures and method of calculating the percent of dry matter shall be as follows:

- (a) At the widest circumference of the avocado remove a core from the entire width of the avocado. Discard the seed portion, and remove the seed coat and the skin to the depth of the edible portion from the remaining core pieces. Cut each core piece in half. The core sample shall be removed with a coring device having an inside diameter of 5/8 inch, plus or minus 1/16 inch.
- (b) Repeat the above for the number of sample fruit required by section 1408.2
- (c) The cored pieces shall be immediately placed in a sealed plastic bag if there is a delay in completing the procedures below.
- (d) Weigh a clean petri dish and record the weight (P).
- (e) Place all core pieces on the preweighed petri dish; reweigh the petri dish with the sample and record the weight (F).
- (f) Place the petri dish with the sample in a 1,000 watt microwave oven and dry the sample at 50% power for 40 minutes, adjusting the power down as necessary to avoid charring the tissue. Remove the sample from the microwave oven and note the weight. Place the sample back in microwave oven for 5 minutes. Remove the sample again and compare weight. If weight is the same, record it as dry weight. Whenever there is a weight difference, repeat this step until there is no weight loss. After the sample reaches a constant weight, record the weight (D).
- (g) Calculate the percent of dry matter using the following example:

$$\frac{D - P}{P} \times 100 = \text{_____ \% dry matter.}$$

All weighings required by this section shall be recorded to the nearest 0.01 gram.

NOTE: Authority cited: Sections 407, 42681, 42684, and 44988, Food and Agricultural Code. Reference: Sections 42941 and 44971, Food and Agricultural Code.

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### Dry Matter %

Adapted from sources listed at bottom of page

#### **Introduction:** How do you tell when the fruit is ripe?

Unlike many fruits, avocado maturity does not coincide with ripeness. An avocado becomes ripe - softens, and so can be eaten - only after it has been picked from the tree, requiring several days at room temperature. It is difficult to know in advance whether an avocado fruit is mature enough to harvest because external appearance of avocado fruit gives only subtle clues to the stage of maturity. The skin loses some of its glossiness, becoming duller; surface russetting increases; varieties that turn black on ripening may become partly so on the tree. When cut open on picking, a mature fruit will slice smoothly, without a crackling sound or rough cut surface. Also, the seed coat will usually be thin and brown instead of fleshy and white.

The ultimate test is picking a fruit and letting it ripen. Mature avocado varieties vary widely in pleasantness of flavor, but an immature fruit of any variety will likely shrivel as it ripens and have a watery, bland, or even "grassy" flavor. You do not want to release such fruit commercially. Therefore, a simple test (closely correlated with taste testing results) was needed to help keep immature fruit off the commercial market.

It has long been recognized that there is a close relationship between the oil content and the development of an avocado fruit. Basically, oil content increases as the fruit matures. The problem was the methods for determining oil content

- Extraction with petroleum-ether in a Soxhlet apparatus and gravimetric determination of oil content; although accurate, it is tediously long and definitely not simple.
- Refractive index (RI) determination of an oil extract with chloronaphthalene; this method had questionable accuracy and chloronaphthalene is suspected of being a health hazard.
- Determination of oil by nuclear magnetic resonance (NMR); accurate but requires expensive equipment.

Then it was discovered that, as oil content increases, the amount of water in the fruit

decreases. Percent dry weight increases during fruit development and the increase is mainly due to the increase in oil. Since it is far easier to analyze percent dry weight than percent oil content, a simple method was soon developed so that any person can easily determine the maturity of his avocado fruit. Minimum maturity standards based on Percent Dry Matter have been determined for many avocado varieties. Click here for the amended dry weight procedures, Department of Food and Agriculture.

## Percent Dry Matter

Materials Needed:

Scale	Calculator
Microwave oven	Food processor with chopping blade
Spatula or spoon	Knife & potato peeler
Petri dish or other small glass dish	Data sheet

### Sampling

Select your avocados carefully. Pick them from the shady part of the tree, from different parts of the grove (if you have a grove). The most immature appearing avocados representing the regular crop should be chosen. Off bloom fruit should not be tested. The fruit must be hard to be tested.

### Procedure

- Fruit are first cut in half (through the seed). Next, lay the flat side down and cut a wedge out of the middle (approximately 1/8th of the fruit). Do this for the other half of fruit. Use these wedges for sampling.
- Using the potato peeler or knife, remove the skin down to flesh. Remove the seed and all traces of the seed coat.
- Cut these wedges into smaller pieces and place into the food processor with a chopping blade. Run the food processor until the avocado has been chopped into fine pieces (starts to stick to the side of the food processor container). Will have the size and consistency of grated Parmesan cheese.
- Reserve several tablespoons of sample in a plastic bag in case the sample needs to be rerun.
- Weigh an empty dish and record its weight... this is the **TARE WEIGHT**.
- Place the empty dish on the scale and add avocado sample until you have added 5 grams. Record this weight on the data sheet. (Does not have to be exactly 5 grams, but within 0.3 on either side... just remember to record the exact weight). This is the **WET WEIGHT**.
- Place the dish containing the finely chopped avocado into the microwave oven.
- Since microwave ovens vary, it is critical to start at a low power setting and gradually work up to higher settings to prevent scorching. Suggested setting might

be 40% power for 15 minutes. After weighing, microwave the sample again for 3 minutes at 40% power then reweigh. This process is repeated at one minute intervals until no further weight loss is observed (after several times of doing this, you can determine the proper power setting and approximate time... just be sure NOT to burn the sample).

- After no further weight loss, remove the sample and weigh... this is the **DRY WEIGHT**.

### Calculating the Percent Dry Matter

$$\frac{(\text{DRY WEIGHT} - \text{TARE WEIGHT})}{(\text{WET WEIGHT} - \text{TARE WEIGHT})} \times 100 = \% \text{ DRY MATTER}$$

So, if your empty glass dish weighs 3 grams (TARE WEIGHT), the weight with fresh avocado is 8 grams (WET WEIGHT) and your weight after drying is 4 grams (DRY WEIGHT), the calculations would look like this:

$$\frac{(4 - 3)}{(8 - 3)} \times 100 = \% \text{ DRY MATTER}$$

$$\frac{1}{5} \times 100 = 20\% \text{ DRY MATTER}$$

### Sources of Information

Bergh, B. O., J. Kumamoto, P. Chen. 1989. Determining maturity in whole avocados. Calif. Avocado Soc. Yearbook. 73:173-176.

Lee, Seung-Koo. 1982. A review and background of the avocado maturity standard. Calif. Avocado Soc. Yearbook. (1981) 65:101-109.

Rosenthal, I., U. Merin, G. Popel, and S. Bernstein. 1985. An analytical assay for the determination of oil content in avocado. Calif. Avocado Soc. Yearbook. 69:133-136.

Amended dry weight Procedures, Department of Food and Agriculture. Title 3. California Code of Regulations

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ACLM/"dry weight" AND ACLM/"vitamin" AND ISD/1/1

PAT.	Title
NO.	

- 1 [6,827,956 T Modified oat and corn grit products and method](#)
- 2 [6,740,332 T Edible film formulations containing maltodextrin](#)
- 3 [6,730,504 T Bacillus natto culture extract](#)
- 4 [6,656,493 T Edible film formulations containing maltodextrin](#)
- 5 [6,645,536 T Micro-particulate microbound diet for the culture of larval fish and crustaceans](#)
- 6 [6,610,335 T Modified oat and corn grit products and method](#)
- 7 [6,599,394 T Soft absorbent tissue treated with a chemical composition](#)
- 8 [6,558,718 T Nutrient clusters for food products and methods of preparation](#)
- 9 [6,514,523 T Carrier particles for drug delivery and process for preparation](#)
- 10 [6,335,388 T Prolamine-plant polar lipid composition, its method of preparation and applications thereof](#)
- 11 [6,232,294 T Neuro-function regulatory agent](#)
- 12 [6,204,244 T Amino acid compositions and use thereof in immunosuppression](#)
- 13 [6,171,635 T Coffee substitute](#)
- 14 [6,153,228 T Propolis extract](#)
- 15 [6,146,825 T Encapsulation of oleophilic substances and compositions produced thereby](#)
- 16 [6,086,917 T Tablet containing an enzymatically converted starch derivative encapsulating agent](#)
- 17 [6,022,555 T Animal feed containing carboxylic acids](#)

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